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Patient Reported Outcomes of Urinary Incontinence Rates Using Viable Cryopreserved Umbilical Tissue Over Neurovascular Bundles During Robotic Assisted Radical Prostatectomy

Samantha Kraemer

Mit Shah

Chirag Dave

JI Qi

Fionna Sun

See next page for additional authors

Authors

Samantha Kraemer, Mit Shah, Chirag Dave, JI Qi, Fionna Sun, Sugandh Shetty, Brian Seifman, and Jason Hafron

Poster #23

PATIENT REPORTED OUTCOMES OF URINARY INCONTINENCE RATES USING VIABLE CRYOPRESERVED UMBILICAL TISSUE OVER NEUROVASCULAR BUNDLES DURING ROBOTIC ASSISTED RADICAL PROSTATECTOMY

Samantha Kraemer, MD[1], Mit Shah, MD[1], Chirag Dave, MD[1], Ji Qi, PhD[2], Fiona Sun[3], Sugandh Shetty, MD[1], Brian Seifman, MD[1], Jason Hafron, MD[1]
[1]Beaumont Health, Royal Oak, MI, [2]University of Michigan, Ann Arbor, MI, [3]Oakland University William Beaumont School of Medicine, Royal Oak, MI
Presented By: Mit Shah, MD, BS

Introduction: Incontinence remains a side effect from robotic assisted radical prostatectomy (RAP) for prostate cancer despite nerve sparing (NS) techniques. Use of growth factors and anti-inflammatory substances over neurovascular bundles is an emerging technique to enhance recovery of continence and potency. Viable cryopreserved umbilical tissue (vCUT) is FDA approved for homologous use in surgery. The objective is to determine if vCUT use in NS-RAP accelerates return to continence.
Methods: Retrospective review of 176 patients who underwent NS-RAPs from October 2015 through July 2020 were identified through the Michigan Urological Surgery Improvement Collaborative (MUSIC). Return to social urinary continence (0-1 pads per day) at 3 months postoperatively was evaluated using MUSIC patient-reported outcome (PRO), a validated questionnaire to assess urinary and sexual issues at baseline and after treatment. Multivariable logistic regression model was used to assess association between the use of vCUT as social continence.
Results: We identified 112 vCUT patients and 64 non-vCUT patients who underwent NS-RAP during our time frame. Based on MUSIC-PRO data, continence was achieved by 3 months post-op in 87% (97/112) of v-CUT patients versus only 72% (46/64) in non-vCUT patients (p=0.016). On multivariable analysis (controlling for age, BMI, diabetes, and baseline continence), although not reaching conventional statistical significance, vCUT patients were more likely to achieve continence than non-vCUT patients (OR=2.29, p=0.06).
Conclusion: Using vCUT during NS-RAP may promote quicker return to social urinary continence. Further larger studies with longer follow up are required to evaluate effectiveness of vCUT to enhance return of continence and potency.
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Poster #24

THE ASSOCIATION OF ELIGIBILITY CRITERIA WITH PROSTATE CANCER CLINICAL TRIAL FAILURE

Kristian Stensland, MD, MPH[1], Samir Hafez[1], Lucas Clarke[2], Sam Kaffenberger, MD[1], Brent Hollenbeck, MD, MS[1], Ted Skolarus, MD, MPH[1]
[1]University of Michigan, [2]Harvard University
Presented By: Kristian D. Stensland, MD, MPH

Introduction: Poor enrollment is the primary barrier to successful clinical trials, yet root causes remain under studied. Restrictive eligibility criteria may lead to poor enrollment by limiting the eligible patient pool. For these reasons, we identified associations of phase 3 prostate cancer clinical trial eligibility criteria with trial enrollment and completion.
Methods: We queried ClinicalTrials.gov for completed or terminated phase 3 prostate cancer trials registered since 2007. We manually coded eligibility criteria and trial failure reason. We compared trial failure and enrollment sufficiency between trial types using Fisher's exact test.
Results: We identified 250 trials, of which 227 (91%) were completed, 4 (2%) ended early for toxicity/efficacy, and 19 (8%) failed. Of all trials, 30% had any kidney eligibility criteria, and 30% had any liver eligibility criteria. Most trials (61%) had a performance status requirement. Eligibility criteria were nearly identical in failed and successful trials ($p \approx 1$ for each comparison).
Conclusion: Successful and unsuccessful phase 3 prostate cancer clinical trials had similar eligibility criteria. The extent to which eligibility criteria reflect or restrict eligible patient populations for trials warrants further study given poor overall enrollment. Better